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IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/394,020	09/10/99	PEPICELLI	C HUV-032.01

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HM12/0507

EXAMINER

ANDRES, J

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/07/01 *24*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p>09/394,020</p>	<p>Applicant(s)</p> <p>PEPICELLI ET AL.</p>	
	<p>Examiner</p> <p>Janet L Andres</p>	<p>Art Unit</p> <p>1646</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's priority claim based on provisional application 60/099952, filed September 11, 1998, is acknowledged.

Election/Restrictions

2. Applicant's election with traverse of group I and species election of SEQ ID NO: 15 in Paper No. 23 is acknowledged. The traversal is on the ground(s) that the search and examination can be made without undue burden and note that the groups are classified in the same class and subclass. Applicant concludes that the restriction requirement is in error and that the Examiner has not shown that a serious burden would be required. This is not found persuasive. MPEP § 808.02 states: Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together.

In the instant application, the claimed methods require entirely different molecules with different structures and functions and a different status in the art. Thus, it is necessary to search for each in places that would not refer to any of the others, and the fields of search are therefore different.

Applicant's comments with respect to the election of species are acknowledged. MPEP § 809.02(a), however, more precisely states that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR

1.141, not that applicant will be entitled to “search and examination of a reasonable number of species”.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims are drawn to methods using hedgehog proteins to affect the growth of lung tissue. However, neither the instant specification nor the prior art provides sufficient guidance for one of skill to use the invention as claimed.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). Here, Applicant has described the phenotype of a null mutant of sonic hedgehog. Applicant concludes that SHH is required for formation of the transesophageal septum, lung lobation, and generation of the respiratory tree (p. 70). These results do not,

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however, indicate to one of skill how SHH or any other hedgehog protein might be used to affect any disease or condition or to modulate growth or proliferation of lung tissue. While a list of diseases of the lung is provided on p. 16, applicant has provided no guidance predictive of anything other than a role in development. No diseases or conditions known to be affected by hedgehog proteins are set forth and no specific function of hedgehog proteins that would allow the artisan to predict what diseases or conditions might be so affected is described. One of skill would not be able to predict, based on a lack of lobation and branching in a null mouse, how hedgehog proteins might modulate the growth state of lung tissue or cells. Applicant states on p. 70 that the exact role of SHH in branching is unknown. The results obtained with a null mutant thus do not indicate to one of skill what effect exogenous hedgehog proteins would have on fully formed tissue or on cells derived therefrom. Further, no examples are presented that would provide guidance as to what results or therapeutic benefit might be expected. The effect on downstream mediators provides no information as to how the proteins might usefully function. The prior art further fails to provide compensatory teachings. Mice overexpressing SHH appear to demonstrate increased mesenchymal cell proliferation; such mice die soon after birth (Bellusci et al., Development, 1997, vol. 124, pp.53-63). There is no nexus provided, either by Bellusci et al. or the instant specification, between the developmental effects of hedgehog proteins and any therapeutic benefit for lung tissue. Thus, without further guidance indicative of how hedgehog proteins might be used to affect any particular condition, it would require undue experimentation for one of skill to use the invention as claimed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is drawn to method comprising “ectopically contacting” tissue. One of skill would not be able to determine what was “ectopic”, which is defined as “out of place” by the American Dictionary of Science and Technology: the tissue, the agent, or the point of contact.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “encodable” and “stringent conditions”. One of skill would be unable to determine a distinction between a sequence that is “encodable” by a polynucleotide and one that is encoded by such a polynucleotide. Stringent conditions are not defined in the specification.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of “growth state” and “hedgehog therapeutic”. Applicant states on p. 14 that “growth state” refers to the rate of proliferation and state of differentiation. This reference does not constitute a definition; one of skill would not be able to determine precisely what is intended to be modulated. The definition of “hedgehog therapeutic” on p. 11 encompasses agonists, antagonists, and mimetics that modulate growth and differentiation of lung tissue. One of skill would not be able to determine from this definition which molecules were included and which were excluded from Applicant’s claims.

Claims 6-17 are rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of “bioactive”. No particular bioactivity for hedgehog proteins is defined.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
May 4, 2001


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600